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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,329	11/09/2001	Michael Baudino	11738.00050	4048
27581	7590	10/04/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/053,329	Applicant(s) BAUDINO ET AL.	
	Examiner Michael J. Hayes	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86,89-107 and 110-141 is/are pending in the application.
- 4a) Of the above claim(s) 1-79 and 110-141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-86 and 89-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the delivery device connected to a first catheter through a first catheter port to a second catheter through a second catheter port as recited in claim 85, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The amendment filed 6/21/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: setting on a delivery pump that adjusts frequency of delivery and amount. Applicant has not provided any citations to show that this amendment was part of the application as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-86, 89-102, and 107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe various limitations recited in the new claims 80-86, 89-107. It appears that these limitations are new matter: catheter protruding from the cannula as recited in claim 80, the delivery device coupling through ports as recited in claim 85, determining liquid infusion rate through first and second catheters with a parameter and signal level as

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recited in claim 91, use of parameters and settings to control liquid infusion as recited in claims 92-98, the sensor in the proximity of liquid delivery position as recited in claim 104, and the treatment of a neurological disorder using catheter and fluid delivery.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis in the specification for setting as used in claims 95-98.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 80, 81, 82, 83, 85, 86, 89, 103, and 107 are rejected under 35

U.S.C. 102(e) as being anticipated by GILLIS et al. (US Publication No. 2003/0069541).

Gillis discloses a delivery system having first and second catheters 60 protruding from a multiple opening cannula 10 and a therapy device (50 and hub) that couples to the first and second catheters. Gillis discloses that the use of replenishment ports is well known in the art to allow for injection of additional drug [0008]. Fig. 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80, 81, 85, 86, 89, 90, 103, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III (US Patent No. 6,129,685). Howard discloses a delivery system with first and second catheters extending from a cannula to deliver a drug and a pump that supplies the liquid medication in the embodiment shown in fig. 30. In this embodiment Howard does not show a plurality of openings in the cannula. In the embodiment shown in figs. 23 and 25 Howard shows a plurality of openings to direct drug delivery to different locations. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of the embodiment shown in figs. 23 and 25 in the embodiment shown in fig. 30 to treat different areas of a patient.

Claims 82-84, 91-102, and 104-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III in view of ELSBERRY et al. (US Patent No. 5,711,316). Howard discloses the claimed invention except for the port, sensor and processor control of the infused liquid from the pump, and timer. Elsberry discloses these limitations to facilitate the delivery of the correct dosing of drug for treating a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Elsberry in the system of Howard to appropriately administer medication to treat a patient.

Response to Arguments

Applicant generally argues that the rejections under 112(1) should be withdrawn because there is support in other patents, incorporated by reference. Applicant has not provided the citation (col., lines) where such support can be found and the examiner maintains the rejections, as discussed above.

Applicant does show the first and second catheters and catheter ports, as claimed in claim 85. Applicant reference to figs. 4-8, 10A, and 11 do not show this plurality.

Applicant argues that the claims rejected under 35 USC 112 have support in various patents; however, Applicant has not provided citations to these patents and has not provided any evidence that these limitations were present in the application as filed.

Applicant argues that support for claim 107 is found on pg. 19, line 10. This location describes the treatment of neurological disorders using an electric field, not delivery of liquids by catheter.

Applicant argues that Gillis does not disclose openings capable of directing a catheter in distinct predetermined trajectory. The examiner disagrees because the openings shown in figs. 4-6 are distinct and would be capable of distinct trajectories.

Applicant's generally argues that Howard does not show particular limitations, but Applicant is reminded that Howard is used in a rejection under 35 USC 103. With regards to the obvious rejections Applicant argues that the openings shown in fig. 25 are not capable of directing a catheter outward. The examiner disagrees in view of the openings disclosed which show this capability as the distal end of lumens.

Applicant's arguments that combining references would not be successful is unconvincing given the nature of the mechanical arts and their combinability.

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Applicant's arguments re the teachings of Howard to modify fig. 25 misinterprets the rejection made in the last office action. The rejection with regards to Howard modifies fig. 30 with the teachings of figs. 23 and 25 with motivation as discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
27 August 2005



MICHAEL J. HAYES
PRIMARY EXAMINER